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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,694	04/03/2002	Akihiko Sano	0020-4976 P	5505

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,694	SANO ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment 09/24/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. While the specification at page 7, lines 13-14 disclose "particles may be those which maintain the solid form in the formulation at a body temperature", it appears that nowhere in the specification disclose the limitation "the solid formulation" as recited in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. US 5,324,519.

Dunn teaches a composition comprising biodegradable polymer capable of forming a biodegradable microporous, solid or gelatinous polymer matrix useful as an implant in animals (see abstract). The composition comprises an active agent, a thermoplastic polymer, a pore forming agent, and a curing agent (column 2, lines 11 through column 3, lines 1-10). The active agent can be selected from vaccines (column 12, lines 33-35).

Dunn is silent as to the teaching of particle containing carbonate, however, it is the position of the examiner that the polymer matrix of Dunn contains carbonate because Dunn teaches that the prepolymer ingredients may release a pore-forming moiety such as, carbon dioxide and the like (column 2, lines 66-68). Accordingly, such language indicates that the organic solvent or the pore forming agent, which is the claimed substance that reacted with the carbonate to generate carbon dioxide. Thus, it would have been obvious for one of ordinary skill in the art to modify the biodegradable polymer composition of Dunn to include the carbon in the matrix with the expectation to

provide a polymer composition that can be administered to an implant site by injection without the need for surgical incision.

Claims 1 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujioka et al. US 4,985,253 and Dunn et al. US 5,324,519.

Fujioka teaches a sustained release composition comprising active core and silicone elastomer as a carrier (column 2, lines 17-27). The composition further comprises stabilizer, preservative, soothing agent, solubilizer, plasticizer, and release controlling agent (column 4, lines 40-60). The composition is suitable for implantation into body cavity of the like (column 5, lines 6-12).

Fujioka is silent as to the teaching of vaccine as the active agent.

Dunn teaches an implantable composition comprising biodegradable polymer capable of forming a biodegradable microporous, solid or gelatinous polymer matrix useful as an implant in animals (see abstract). The composition comprises vaccine as an active agent (column 12, lines 33-35). Thus, it would have been obvious for one of ordinary skill in the art to modify the sustained release composition of Fujioka using vaccine as the bioactive agent in view of the teaching of Dunn with the expectation to provide a sustained release implantable composition that can be administered to an implant site by injection without the need for surgical incision.

Response to Arguments

Applicant's arguments filed 09/24/04 have been fully considered but they are not persuasive.

Applicant argues that Dunn teaches a liquid formulation. The abstract of Dunn recites the word "solid" does not qualify the "composition" itself of the intended invention of Dunn. Contrary to the applicant's argument, as discussed in the 112, 1st paragraph rejection above, it appears that applicant's specification does not disclose a "solid composition" itself. It is noted that Dunn teaches the particles that maintain solid form as desired by the applicant. See column 4, lines 58-63, wherein upon contact with an aqueous fluid and the solvent, the thermoplastic polymers are capable of coagulating or solidifying to form a solid matrix suitable for use as an implant. Furthermore, Dunn teaches that the formulation in situ forms a solid implant confirming to the shape or the contour of the site, and the composition is useful in overcoming placement difficulties inherent with solid forms of implants (column 4, lines 14-15). Accordingly, there're no unexpected results between the claimed formulation and that of Dunn.

Applicant argues that the combination of Dunn and Fujioka is not an appropriate combination to deny the unobviousness, because Fujioka describes a solid formulation, and because Fujioka fails to describe any solid formulation comprising a carbonate. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d

413, 208 USPQ 871 (CCPA 1981). Furthermore, it is noted that the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Fujioka is cited as a primary reference. Dunn is cited in combination with Fujioka solely for the teaching of vaccine as an active agent.

Applicant's states that the unexpected results showed that the claimed invention released latex beads at the rate of more than 30 µg/ml, whereas reference formulation 2 (similar to the formulation of Fujioka) released latex beads merely at 0.1 µg/ml. Thus, the claimed formulation of the present invention accelerates the release of an active ingredient more than 300 times when compare to formulations like those of Fujioka. In response to applicant's argument, first, applicant has not provided a side-by-side comparison showing unexpected results over the cited references. Second, the rate of release is not being claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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